Summary of Public Comments

Collection of Data on Specialized Cardiac Care Services: Percutaneous Coronary Intervention Services (Primary and Non-Primary) and Cardiac Surgery

For Review and Discussion at the December 7, 2009 Meeting of the PCI Data Work Group

Introduction

The Maryland Health Care Commission (MHCC) defines specialized cardiac care to include three major services: (1) emergency angioplasty, referred to as primary percutaneous coronary intervention (pPCI) services, for certain types of heart attacks or ST elevation myocardial infarctions (STEMIs); (2) elective or non-primary PCI; and, (3) cardiac surgery. There are currently ten Maryland hospitals that offer all three specialized cardiac care services. In addition, thirteen Maryland hospitals without cardiac surgery on-site provide pPCI services under a waiver program established by the Commission.[1]

Under COMAR 10.24.17[2] and COMAR 10.25.04[3], the Commission collects data on patients receiving specialized cardiac care services. The Commission is interested in adopting a standard data set for each category of specialized cardiac care service that will provide high quality and timely data measuring the process and outcomes of care. To obtain stakeholder input on alternative approaches, a Request for Public Comment was posted on the Commission's website on September 28, 2009. The Commission requested comment on the following questions:

- Should the Commission establish a Maryland STEMI database to include all hospitals providing pPCI services?
- Should the ACTION Registry®-GWTG™ be adopted as the standard data set required for all Maryland pPCI patients?
- Should the Commission adopt the NCDR CathPCI Registry® data base for PCI services?
- Should the Commission adopt the STS Adult Cardiac Surgery database for adult cardiac surgery services?

The Commission received comments from 15 organizations in response to the Request for Public Comment:

Adventist HealthCare
American College of Cardiology (Maryland Chapter)
American Heart Association
Anne Arundel Medical Center
Carroll Hospital Center
Frederick Memorial Healthcare System

[1] Nine of these hospitals have been approved by the Commission to participate in a research study of non-primary PCI in hospitals without cardiac surgery on-site.
[2] COMAR 10.24.17.05D(1) State Health Plan for Facilities and Services: Specialized Health Care Services-Cardiac Surgery and Percutaneous Coronary Intervention Services, Waiver from Policies, Primary Percutaneous Coronary Intervention in Hospitals without On-Site Cardiac Surgery. Table A-1, Process and Outcome Measures for Ongoing Quality Assessment.
[3] COMAR 10.25.04.02B, Hospital Quality and Performance Evaluation System, Hospital Evaluation—Data Collection and Reporting Requirements.

Holy Cross Hospital
Johns Hopkins Health System
MedStar Health
Maryland Institute for Emergency Medical Services Systems (MIEMSS)
Peninsula Regional Medical Center
Southern Maryland Hospital Center
Society for Cardiovascular Angiography and Interventions
University of Maryland Medical Center
Western Maryland Health System

(The full text of the comments submitted by each organization is provided in Attachment 1.)

Percutaneous Coronary Intervention Services (Primary and Non-Primary PCI)

- **Should the Commission establish a Maryland STEMI database to include all hospitals providing pPCI services?**

Adventist HealthCare (AHC) supports the establishment of a Maryland STEMI data base by MHCC to include all hospitals within the State. In addition, MHCC should consider a number of issues that require further analysis, including but not limited to: (1) the effect of public outcomes reporting on the treatment of high risk patients; (2) recognition of the importance of appropriate risk stratification factors; and, (3) appropriate use of statistical methods for risk adjustment.

American College of Cardiology, Maryland Chapter (ACC-MD Chapter) supports the establishment of a Maryland STEMI database to include all hospitals providing pPCI services, provided that the sole purpose of the database is to improve the systemic delivery and outcomes of patients suffering a STEMI in Maryland. According to ACC, the Commission currently publicly reports institutional volumes and door-to balloon times, which only provide a partial and limited view of the overall quality of care. ACC recommends that Maryland provide adequate additional funding to the participating institutions to cover any additional cost burden of data collection. The ACC-MD Chapter has no financial conflict of interest relevant to any clinical data registry.

Carroll Hospital Center (CHC) recommends that all hospitals, including those providing on-site cardiac surgery, be monitored via an established database.

Holy Cross Hospital (HCH) encourages the Commission to require all players to participate. HCH strongly believes the State would benefit from having data from all hospitals performing PCI, not just those operating under a waiver. HCH notes that this would provide a better picture of how well cardiac needs are being met across the State and the ability to benchmark and track cardiac quality indicators for Maryland hospitals.

MedStar Health, on behalf of its affiliated institutions, encourages the Commission to act cautiously when considering imposing additional data collection requirements on hospitals. MedStar believes that the work group proposed to follow up on this request for comment is the best approach. The work group should consider, in addition to the specific issues of data collection and database development, issues such as: (1) clarifying multiple uses of the data (regulatory decisions, planning, and outcomes reporting); (2) inclusion of sunset provisions given the time-limited nature of the waivers; (3) financial burden on hospitals; (4) timeframe for implementation of new systems; (5) provisions for out-of-state hospitals to participate in the registry, in anticipation of being designated as a STEMI referral center; and, (6) special

considerations regarding the availability of the data to hospitals and the public. In addition, MedStar would be pleased to offer representatives to the MHCC's work group to further discuss the implications of database development and expanded data collection.

Maryland Institute for Emergency Medical Services Systems (MIEMSS) wrote that it believes all Maryland hospitals that provide pPCI should be included and required to submit data to MHCC. Currently, data is available only for hospitals that have received a waiver from the MHCC to provide pPCI. AHA and ACC guidelines recommend all hospitals providing pPCI meet certain standards including operator and institutional volume requirements as well as door-to-balloon times of less than 90 minutes for 75% of appropriate patients. Maryland currently does not have a system in place to measure the performance and outcomes of all hospitals providing pPCI.

Peninsula Regional Medical Center (PRMC) notes that pertinent information, similarly collected in the Maryland STEMI database, is tracked at its institution as part of the AMI core measure and door-to-balloon-time. PRMC added that the data are readily available as part of the hospital core measures reporting. PRMC expressed concerns with mandatory participation in several data registries as it may not prove cost-effective or even beneficial. Participating in registries requires significant fees from the facilities and even greater costs for data collection and reporting. PRMC believes that before mandating any new costs for hospitals and the physicians who practice, that the Commission should show that it expects a reasonable return on investment and a willingness to fund that investment. According to PRMC, in New York there is no statistically significant difference in the outcomes of almost all facilities. As a result, PRMC states that it is not evident that the data collection efforts are yielding any benefits for patients.

Southern Maryland Hospital Center (SMHC) strongly supports the proposal to establish a Maryland STEMI database to include all hospitals providing pPCI services, including both hospitals holding a pPCI waiver and hospitals providing on-site cardiac surgery services. In order to assure high quality and timely data on specialized cardiac care, SMHC suggests that the Commission adopt a uniform data set to be provided by all the providers of such care in a consistent fashion. Currently, the SEXTANT database requires the submission of documents to validate various key elements, including documents that provide the patient's arrival and balloon time. The existing process includes an audit and validation process. SMHC recommends that a similar process be implemented in conjunction with the designation of a new registry database.

The Society for Cardiovascular Angiography and Interventions (SCAI) supports reporting of outcomes by all centers in the State that care for STEMI patients. SCAI believes this process will allow for a more fair and balanced approach to looking at outcomes across hospitals within the State. According to SCAI, steps should be taken to ensure that unintended consequences are not the result of publicly reporting data. Publicly reported data should identify only observed differences that are statistically significant. The fact that Maryland does not provide these important statistical measures in the data that it currently posts to the web on door-to-balloon times from its Maryland STEMI (Primary PCI) Data Registry report may mislead patients into making decisions based on reported differences that are not statistically significant. Another unintended and potentially unfortunate result of public reporting may be that the patients who

need interventions will find their physicians reluctant to treat them. Similarly, for patients with riskier prognoses and living near the Maryland State line, there may be an incentive to transfer/refer these patients out-of-state for treatment. According to SCAI, steps can and should be taken to avoid these unintended consequences.

University of Maryland Medical Center (UMMC) believes that MHCC should establish a Maryland STEMI database to include all hospitals providing pPCl services. UMMC strongly recommends that if all hospitals are included that the MHCC establish a minimum threshold for the number of STEMI patients cared for at the hospital to be considered for inclusion in the database. Although most of the hospitals that perform cardiac surgery see large volumes of STEMI patients transferred from outside hospitals, only those STEMI patients admitted from their Emergency Departments are publicly reported. In addition, the patients seen at hospitals with cardiac surgery have a higher acuity mix and may look very different from patients currently cared for by community hospitals without cardiac surgery programs. Therefore, the small volume of STEMI patients admitted via the ED reported at these facilities may not be a fair comparison with high volume community hospitals in the Maryland STEMI database.

Western Maryland Health System (WMHS) comments that it is an active participant in the ACC/CathPCI NCDR, ACTION-GWTG as well as the STS Adult Cardiac Surgery databases. WMHS notes that these registries are considered the "Gold Standard" across the country. According to WMHS, payers are using these databases to establish/designate Cardiac Centers of Excellence. Additionally, participation provides other added benefits such as benchmarking with other facilities along with quality metrics, utilization metrics for both catheterization and intervention, and mortality, both expected and risk-adjusted.

WMHS notes that the data collection process is very labor intensive. Data duplication is a significant concern for those individuals abstracting the data and increases the need for added personnel to collect and submit different standards/measures. The ability to collect and distribute all of the data to one repository allows the measures to then be distributed to the various organizations requiring the data. Additionally, the data is consistent, accurate and based on the same data definitions. This enhances patient outcomes by assuring accuracy in data interpretation and application of the same standards of care to all who are providing the service.

WMHS supports utilization and participation in the nationally recognized registries established by the ACC and STS rather than the development of a separate data base for the State of Maryland.

- **Should the ACTION Registry®-GWTG™ be adopted as the standard data set required for all Maryland pPCI patients?**

Adventist HealthCare (AHC) supported use of the NCDR CathPCI registry if participation is mandated. According to AHC, the ACTION Registry falls short on a series of criteria, most notably its risk-adjustment paradigm. According to AHC, neither the CathPCI or ACTION registry adequately collects follow-up data on patients; which is something that the STS Adult Cardiac Surgery Database (ACSD) tracks. There are concerns that the volume of cases

participants are performing may hamper meaningful results. This is particularly true in the case of hospitals which are operating on waivers, such as with respect to the C-PORT-E trial. The randomization process in this research study of non-primary PCI hampers the facility's volume. Without a significant volume, the statistical analysis will not carry enough merit to make substantive conclusions about how that hospital performs. Quarterly reports on this data could result in misinterpretation.

Additional questions that need to be considered concern whether the MHCC plans to collect the ACC-NCDR quarterly reports or to collect the raw data. Clearly, collecting the raw data provides a more powerful analytical tool at the State level. This is an area that would require further study to alleviate the concerns about how the data is analyzed.

American Heart Association-Mid-Atlantic Affiliate (AHA-Mid-Atlantic) wrote in support of adopting the ACTION Registry®-GWTG™. According to AHA, as it provides MHCC with the best method to track the care of STEMI and non-STEMI patients in Maryland. The ACTION Registry-GWTG tool provides hospitals with the ability to collect a comprehensive set of data elements that will provide health care professionals and their facilities with the information they need to monitor and improve adherence to the most current, science-based American College of Cardiology/AHA treatment guidelines. Participation in this registry helps hospitals facilitate quality improvement efforts, optimize clinical care, and improve clinical outcomes for their patients.

In addition to providing hospitals with the internal means to monitor inpatient care, ACTION Registry-GWTG also provides the opportunity to see how the full system of care is performing. The program allows tracking from first medical contact with EMS to care received at/between multiple hospitals, should the patient need to be transferred from a non-PCI-capable facility to one that has primary PCI-capabilities. For this reason, ACTION Registry-GWTG will function as the primary data tool for the AHA's Mission: Lifeline program. Through Mission: Lifeline, the AHA wants to ensure that health care systems are able to deliver prompt and appropriate care to STEMI patients during the critical "golden hour" following their heart attack. The overarching goal of the initiative is to reduce mortality and morbidity for STEMI patients and to improve their overall quality of care.

According the AHA-Mid-Atlantic, MIEMSS selected Get with the Guidelines–Stroke (GWTG–Stroke) as the quality improvement tool for all primary stroke centers in Maryland. To date, 35 Maryland hospitals are using GWTG–Stroke and submitting data to MIEMSS for continuous quality improvement, which is facilitated through the Stroke QIC (Quality Improvement Committee). GWTG–Stroke allows MIEMSS and each hospital to monitor their adherence to guidelines and benchmark improvements against other Maryland hospitals, as well as nationally. Over 16 hospitals in Maryland have been recognized with GWTG–Stroke achievement awards, based on their improved performance in meeting guidelines.

American College of Cardiology- Maryland Chapter (ACC-MD Chapter) comments that it would not oppose the adoption of the ACTION Registry®-GWTG™ provided that all hospitals that treat acute MI patients are required to participate. The ACC believes the NCDR CathPCI

Registry, which is more widely used, can provide the appropriate data, thereby minimizing an additional administrative burden to the hospitals and the State.

Anne Arundel Medical Center (AAMC) notes that the registry systems under consideration – ACTION Registry®-GWTG™ as well as the NCDR CathPCI Registry are databases that are recognized as national benchmarking tools. These registries will aid the State in implementing a surveillance system enabling participating institutions to increase adherence to agreed upon guidelines. According to AAMC, it is important that all hospitals performing PCI services, those with and without surgical backup, be expected to participate. Comments from Maria Geronimo, R.N., Cardiac Program Coordinator for AAMC, supported adoption of the ACTION Registry, GWTG as the standard Maryland data set. According to Geronimo, with the ACTION Registry hospitals would have the ability to track door-to-balloon times and other important measures.

Carroll Hospital Center (CHC) currently follows all recommendations from the American Heart Association's Get with the Guidelines program. CHC has access to the ACTION Registry®-GWTG™ , but Carroll Hospital Center's automated database currently reports STEMI cases to the NCDR CathPCI Registry.

Holy Cross Hospital (HCH) supports the ACTION Registry®-GWTG™. HCH notes that the Action Registry is a good tool for capturing and comparing data for primary PCI (for STEMI), as well as for all myocardial infarction (MI) patients (STEMI and non-STEMI). However, HCH notes that it may not be robust enough to capture data on all MIs and other unstable/ stable angina patients needing a PCI; or meet the Commission's need for data quality, as it does not include a mechanism for independently checking and validating the data entered by individual sites into the registry. HCH recommends that the State adopt a single database and establish criteria for data validation for that database.

Maryland Institute for Emergency Medical Services Systems (MIEMSS) supports Commission adoption of the ACTION Registry®-GWTG™ as the standard data set for hospitals that provide pPCI services. According to MIEMSS, the ACTION Registry®-GWTG™ is a comprehensive data set for hospitals that provide pPCI services. MIEMSS strongly encourages the inclusion of pre-hospital data in the database that is adopted as the standard for use by the MHCC. MIEMSS referenced preliminary discussions with the AHA and ACC regarding ACTION Registry®-GWTG™, and noted that pre-hospital data elements could potentially be incorporated in to the ACTION Registry®-GWTG™ database. MIEMSS believes that with the addition of the pre-hospital data elements, the ACTION Registry®-GWTG™ would be an ideal standard data set for use by Maryland hospitals providing pPCI. Additionally, MIEMSS notes that Maryland hospitals designated as primary stroke centers use GWTG-Stroke as the standard data set for stroke patients. Benefits include the ability of hospitals to benchmark performance against State and national data as well as MIEMSS' ability to monitor trends in the statewide stroke system of care for Maryland. MIEMSS has been very satisfied with GWTG-Stroke and has received positive feedback from the primary stroke center coordinators that work with GWTG–Stroke at their facilities.

Southern Maryland Hospital Center (SMHC) currently participates in the ACTION Registry®-GWTG™ and is able to provide data using this database. SMHC, however, expresses concern that this database, as currently configured, would not capture all of the data currently reported using the SEXTANT database. The ACTION Registry®-GWTG™ includes up to eight or ten extra fields which could potentially be customized to include additional data. The ACTION Registry®-GWTG™ also appears to be more focused on quality improvement initiatives and appears to offer more flexibility and adaptability than other databases. SMHC noted their concern regarding the validation of data. The ACTION Registry®-GWTG™ does not have a well-defined validation process to ensure that all elements are submitted accurately.

The Society for Cardiovascular Angiography and Interventions (SCAI) states that the ACTION Registry®-GWTG™ is a relatively new and untested registry that is designed for use in all hospitals that treat patients with acute myocardial infarctions (MIs). According to SCAI, this registry is currently used in only a small fraction of all hospitals nationwide. SCAI believes that since the registry is funded by pharmaceutical manufacturers, exempting hospitals that only provide medical therapy to acute MI patients does not seem appropriate. SCAI does not support mandating participation in this registry at this point in time for any Maryland hospitals.

University of Maryland Medical Center (UMMC) supports MHCC in the adoption of the new jointly created ACTION Registry®-GWTG™ standards sponsored by the American Heart Association and the American College of Cardiology. UMMC currently participates in the American College of Cardiology's NCDR CathPCl Registry instrument. UMMC strongly believes with the adoption of this national registry, MHCC should create a quality control and quality auditing process to assure data integrity. It recommends that MHCC consider the development of an education and credentialing process on data reporting and the development of a monitoring and audit function to assure data integrity.

- **Should the Commission adopt the NCDR CathPCI Registry® data base for PCI services?**

American College of Cardiology-Maryland Chapter (ACC-MD Chapter) supports the adoption of the NCDR CathPCI Registry database for PCI services. It affirms its approval if the registry adoption is accompanied by a firm assurance from the MHCC that this database will NOT evolve into a public reporting system without input from all interested parties including the NCDR and the MD-ACC. Any reporting of institution specific patient clinical outcomes should be meticulously risk-adjusted and adjudicated. All stakeholders should be given the opportunity to work with the MHCC to minimize unintended negative consequences from public reporting due to incomplete risk-adjustment or the reporting of non-statistically significant differences. The NCDR CathPCI Registry includes a PCI in-hospital, risk-adjusted mortality model that has the National Quality Forum endorsement as part of quarterly benchmark reports, and will be expanding to risk-adjustment metrics for vascular complications and major bleeding events in 2010.
All NCDR registries feature electronic data capture, either through a complimentary web-based data collection tool provided as part of the enrollment fee or certified software vendors, which offer options to customize the electronic data collection from existing hospital data systems.

All NCDR registries also provide quarterly comparative institutional outcomes reports to enable benchmarking with peers and the national experience; access to clinically experienced customer support staff; and, participant training resources (e.g., user manuals, workshops, and annual user group meetings).
NCDR registries require hospitals to submit data on 100 percent of patients that meet the inclusion criteria. By receiving data directly from the NCDR, the MHCC can take advantage of the NCDR's data validation process that automatically reviews quarterly data submissions for completeness before accepting data for aggregation, and provides hospitals with immediate feedback regarding incomplete submissions.

Anne Arundel Medical Center (AAMC) notes that the NCDR CathPCI registry is a database recognized as a national benchmarking tool. The registry aids the State in implementing a surveillance system enabling participating institutions to increase adherence to agreed upon guidelines. AAMC believes it is important that all hospitals performing PCI services, those with and without surgical backup, be expected to participate. Any effort to organize a statewide systems of collecting data on specialized cardiovascular services is a positive move towards developing a continuous process of improvement in the care of cardiac patients. This endeavor will improve the ability to collect meaningful data that could be used in a collaborative effort. AAMC also believes that the data could be used in comparing outcomes to volume-based peer groups nationwide and aid in the implementation of evidence based guidelines throughout the State of Maryland.

Carroll Hospital Center (CHC) believes that the NCDR CathPCI Registry is inclusive of all the necessary components to adequately monitor STEMI care. As CHC is currently reporting its data through this mechanism, it prefers this database as the reporting standard for Maryland.

Frederick Memorial Healthcare System (FMHS) notes that because the MHCC pPCI Registry and Sextant sunset at the end of 2009, it advocates statewide reporting for pPCI services (for hospitals with and without open heart surgery capability) through the NCDR CathPCI Registry. Currently, the ACTION registry, although provided at no cost, would require a significant amount of additional data reporting, much of which has no relevance to PCI metrics. In addition, FMHS strongly feels that statewide reporting and compilation of data at the state level should be at no additional cost to FMH other than the cost of membership to the NCDR.
FMHS supports the ongoing reporting to the State of pPCI volumes as well as door-to -balloon times. These two metrics assist FMHS in providing this much needed service to the community. It strongly believes that it should have the ability to understand statewide volumes and door to balloon times from hospitals both with and without surgery on site. However, FMHS cautions that other information and data from the CathPCI registry needs to be interpreted carefully. All information presented statewide should be risk-adjusted and interpreted in an objective fashion. These metrics are owned by each individual hospital and are intricately tied in with other demographic and clinical information which could be subject to misinterpretation at the statewide level in a negative manner by individuals, payors, and other parties.
In regards to npPCI services, FMHS is supportive of on-going data collection and reporting through the C-PORT-E protocol. At this time, FMHS does not believe that statewide reporting outside of C-PORT-E is necessary due to the sensitive clinical and political nature of the npPCI

service. The NCDR CathPCI registry combines many metrics from both pPCI and npPCI services. FMHS feels these metrics could be misinterpreted by other parties and result in public opinion and conclusions outside of the research findings. We believe that the decision of State reporting of npPCI services should be made at the conclusion of the C-PORT-E trial.

Holy Cross Hospital (HCH) does not have enough familiarity with this registry to comment. However, HCH recommends that the State adopt a single database and establish criteria for data validation for the single database.

Johns Hopkins Health System (JHHS) and it four member hospitals strongly support adoption of the ACC NCDR CathPCI Registry data base as the single, standard data base for use by hospitals providing PCI services in Maryland. All four of the JHHS hospitals use the data base, and have found that some payors require participation in order to be eligible for Center of Excellence designations. It notes that adoption of the aforementioned data base helps eliminate duplicative reporting and achieves administrative consistency and efficiency. However, JHHS expresses concern about how information from the CathPCI registry would be used if it were to be adopted for all hospitals performing PCI. Results gathered from the Maryland STEMI Registry are used to enforce the standards for delivery of primary PCI services described in COMAR 10.24.17, but only for hospitals with a waiver that allows them to perform pPCI. Adoption of a single data base and reporting for all hospitals would newly allow external monitoring of primary PCI process and outcome measures for hospitals with cardiac surgery on-site. JHSS also suggests MHCC refine the new door-to-balloon time requirements in COMAR 10.24.17. Johns Hopkins Health System encourages the State to include in regulation for PCI data reporting provision for periodic external data audits, with on-site comparison of submitted data with source material; and, to support audits with adequate ongoing funding.

Medstar Health's affiliated institution, Union Memorial of Baltimore; belongs to the ACC CathPCI registry. It believes the registry is well established and nationally recognized as the Gold Standard in the field. It notes that this allows for national benchmarking and meaningful comparisons as many hospitals nationally participate in this registry.

Peninsula Regional Medical Center (PRMC) favors adoption of the NCDR CathPCI Registry as it no longer participates with the ACTION Registry. It, however, has reservations about mandatory participation in several data registries as it may not be cost beneficial. PRMC believes the Commission should proceed with extreme caution for any state mandate of data collection. It noted that participants in the NCDR own their own data and the site specific data cannot be released without the site's permission. PRMC worries that the Commission could compel facilities to make those data public and such releases may not provide a comprehensive risk-adjustment methodology and a sophisticated, but easily understandable presentation of the statistical significance of any observed differences. It notes that statistical significance at the physician level is even more difficult to obtain and should probably not even be attempted until valid data are available at the facility level.

The Society for Cardiovascular Angiography and Interventions (SCAI) recommends mandated NCDR data collection in Maryland if the decision is accompanied with firm

assurances that: (1) it wouldn't rapidly evolve into a public reporting system; (2) the State Government would work with all affected parties to minimize un-intended negative consequences from public reporting due to incomplete risk-adjustment, or the reporting of non-statistically significant differences or similar problems; and (3) the State Government would also evaluate measures of "all cause mortality versus cardiac mortality". SCAI adds that the release of NCDR CathPCI data registry scores would not be in the best interest of patients in Maryland. The data in the CathPCI registry undergoes only minimal auditing, the risk adjustment methodology does not include many important details and adverse outcomes are not adjudicated to ensure that they were related to the performance of the facility, physician or staff. SCAI noticed other States efforts such as the model in Massachusetts. There the government works with data developed through the NCDR process but it iteratively with the affected hospitals to improve data accuracy and they adjudicate the reasons for adverse events in these registries before releasing the data to the public. The adjudication process works to ensure that only adverse events are not random occurrences but related to the quality of care that was delivered to those patients.

- **Should the Commission adopt the STS Adult Cardiac Surgery database for adult cardiac surgery services?**

Adventist HealthCare (AHC) believes that the STS Adult Cardiac Surgery Database would be an excellent starting point for the MHCC to capture cardiac surgery data due, in part, to its inclusive risk-modeling procedure. According to AHC, STS has a high rate of hospital participation. Despite being the gold-standard for cardiac surgery analysis, the STS-ACSD registry has analytical limitations in terms of the 5 strata of cases it assess. According to AHC, defining an isolated CABG can vary, as demonstrated by the work of the Mass-DAC. The Mass-DAC publishes a grid of what they consider to be an isolated CABG and how that contrasts with what the STS considers an isolated CABG. For providers or institutions that operate on high risk patients, there may be more non-standard combination procedures which are often left out of analysis.

AHC recognizes that for the STS Database to apply uniformly throughout Maryland, a statistical algorithm would best be developed to monitor certain cases risk-adjust appropriately. Looking again at the Mass-DAC example, Massachusetts breaks down the data both at the institution level and at the individual operator level. STS has commented that there are known analysis problems when applied at the individual operator level. Of important note on the practitioner - level is that Mass-DAC excludes shock, emergent and emergent salvage cases from that detail of analysis; however, those are included in the institution-level analyses. Furthermore, the volume of cases becomes a factor in this analysis, much like with pPCI. Both, the NY and MA registries address this issue by assessing surgery on a rolling 3-year basis to maintain statistical relevance of the cases. Finally, trying to code what the risk profile of each patient can be a challenge. The Mass-DAC reports show how they had to adjudicate patient reports for risk stratification before analysis and reclassify them accordingly. This is just one example that MHCC should consider.

In the case of cardiac surgery, AHC recommends studying how other States analyze the data. AHC notes that as a published and completed reporting service, the STS database provides the most comprehensive risk-adjustment analysis; however, it is still a limited tool. In addition to the case stratification problem, the STS only calculate their risk-coefficients twice per annum. Therefore, despite providing quarterly data reports, the full reports are semi-annual.

Anne Arundel Medical Center (AAMC) comments that although it does not have an Adult Cardiac Surgical program, it suggests that the STS database would benefit all hospitals caring for cardiac patientsas it is recognized as a national benchmarking tool.. AAMC believes the initiation of this Statewide database will continue the movement down the road of transparency and accountability and benefit hospitals, physicians, nurses and patients. The care of cardiac patients is a shared effort. The practice of measurement, reassessment and improvement is a process to which all who provide cardiac care should adhere.

Johns Hopkins Health System (JHHS) strongly supports the adoption of the STS Adult Cardiac Surgery database in Maryland. In a previous report issued February 2005, JHHS noted that the Quality Measurement and Data Reporting Subcommittee of the Advisory Committee on Outcome Assessment in Cardiovascular Care recommended adoption of the STS database. JHHS suggests that the extensive work of the Subcommittee and the resulting recommendations be used as a foundation and starting point for further discussions regarding data collection and reporting and outcomes assessment in cardiovascular care in Maryland.

Medstar Health's affiliated institution, Union Memorial of Baltimore; belongs to the STS Adult Cardiac Surgery Database. It believes the registry is well established and nationally recognized as the Gold Standard in the field. It notes that this allows for national benchmarking and meaningful comparisons as many hospitals nationally participate in this registry.

University of Maryland Medical Center (UMMC) supports MHCC in the adoption of the STS Adult Cardiac Surgery database with the inclusion of an auditing and monitoring function as described in earlier comments. UMMC understands that all cardiac surgery hospitals in Maryland currently participate in the STS Registry and other states such as California, Pennsylvania and Massachusetts require cardiac surgery programs to report their data to STS. Because the STS data set is widely used, Maryland cardiac programs can benchmark their performance not only against other Maryland programs but also against other top performing programs nationwide. UMMC recommends, as stated earlier, that a quality control and quality auditing function be developed to assure data integrity. It also believes that data should be used for quality improvement purposes and that a consortium of existing cardiac surgery program providers be established for this purpose. The consortium should be physician led with a goal to review and learn from peers on best practices and with the goal to improve the quality of care and outcomes of cardiac care provided by Maryland cardiac surgery programs.